UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,574	09/24/1998	MICHAEL PANACCIO	DAVIE60001AP	6196

20995 7590 02/20/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	24

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/077,574	Applicant(s) Panaccio et al.
	Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 9, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-62 and 92-115* is/are pending in the application.

4a) Of the above, claim(s) *3-5, 11, 13-31, 33-36, 42, 44-62, 92, 93, 96-107 and 110-113* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 6-10, 12, 32, 37-41, 43, 94, 95, 108, 109, 114, and 115* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 12/09/02 (paper no. 23) in response to the non-final Office Action mailed 05/30/02 (paper no. 22).

Status of Claims

2) Claims 1, 6-9, 12, 32, 37-40, 43, 94, 95, 108 and 114 have been amended via the amendment filed 12/09/02.

Claims 1-62 and 92-115 are pending.

Claims 1, 2, 6-10, 12, 32, 37-41, 43, 94, 95, 108, 109, 114 and 115, to the extent these claims encompass the elected invention, are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to claims 12 and 94 made in paragraph 19(b) of the Office Action mailed 08/29/01 (paper no. 16) is withdrawn in light of Applicants' amendment to the claims.

6) The objection to claim 108 made in paragraph 19(c) of the Office Action mailed 08/29/01 (paper no. 16) is withdrawn in light of Applicants' amendment to the claim.

7) The objection to claims 1, 6, 7, 32 and 95 made in paragraph 35(b) of the Office Action mailed 05/30/02 (paper no. 22) is withdrawn in light of Applicants' amendment to the claims.

8) The objection to claims 114 and 115 made in paragraph 35(a) of the Office Action mailed 05/30/02 (paper no. 22) is withdrawn.

Objection(s) Maintained

9) The objection to claim 41 made in paragraph 35(b) of the Office Action mailed 05/30/02 (paper no. 22) is maintained for the reason set forth therein.

Rejection(s) Withdrawn

10) The rejection of claims 38-43 made in paragraph 10 of the Office Action mailed 08/29/01 (paper no. 16) and maintained in paragraph 24 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

11) The rejection of claims 6 and 7 made in paragraph 12(a) and the rejection of claims 8 and 9 made in paragraph 12(k) of the Office Action mailed 08/29/01 (paper no. 16) and maintained in paragraph 24 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

12) The rejection of claim 94 made in paragraph 15 of the Office Action mailed 08/29/01 (paper no. 16) under 35 U.S.C. § 102(b) as being anticipated by Labigne *et al.* (WO 94/26901 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claims 94 and 95 made in paragraph 17 of the Office Action mailed 08/29/01 (paper no. 16) under 35 U.S.C. § 103(a) as being unpatentable over Labigne *et al.* (WO 94/26901 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the claims.

14) The rejection of claims 9 and 38-40 made in paragraph 30 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

15) The rejection of claims 1 and 32 made in paragraph 31 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

16) The rejection of claim 6 made in paragraph 34(b) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 114 made in paragraph 34(c) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 95 made in paragraph 34(d) of the Office Action mailed 05/30/02

(paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claims 94 and 95 made in paragraph 34(e) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

20) The rejection of claims 9 and 40 made in paragraph 34(g) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

21) The rejection of claim 95 made in paragraph 34(h) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

22) The rejection of claim 43 made in paragraph 34(f) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

23) The rejection of claims 6, 7, 32, 37 and 38 made in paragraph 14 of the Office Action mailed 08/29/01 (paper no. 16) and maintained in paragraph 26 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 102(e) as being anticipated by Knittel *et al.* (US 5,714,375) as evidenced by Lemarchand *et al.* (*Vet. Pathol.* 34: 152-156, March 1997, abstract), is withdrawn in light of Applicants' amendments to the claims.

24) The rejection of claims 1, 2, 6-8, 32 and 37-39 made in paragraph 18 of the Office Action mailed 08/29/01 (paper no. 16) and maintained in paragraph 27 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 103(a) as being unpatentable over Joens *et al.* (US 5,610,059), is withdrawn.

Rejection(s) Maintained

25) The rejection of claim 41 made in paragraph 31 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein.

26) The rejection of claims 1 and 2 made in paragraph 14 of the Office Action mailed 08/29/01 (paper no. 16) and maintained in paragraph 26 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 102(e) as being anticipated by Knittel *et al.* (US 5,714,375) as evidenced by

Lemarchand *et al.* (*Vet. Pathol.* 34: 152-156, March 1997, abstract), is maintained for reasons set forth therein and herebelow.

Applicants contend that Knittel *et al.* does not teach an isolated immunogenic component in the antigen of the disclosed attenuated bacteria as required by the presently claimed invention.

Applicants' argument has been considered, but is not persuasive. As set forth at the end of paragraph 26 of the Office Action mailed 05/30/02 (paper no. 22), Knittel *et al.* did teach an isolated, partially purified antigen of *L. intracellularis* that has been passed through a 22 gauge needle, centrifuged to remove cellular nuclei and debris and resuspended in a desired diluent (see Example 5). Such an antigen would inherently be immunogenic. The term "vaccine" in the instant claims is viewed as the intended use of the claimed component and therefore is not given any patentable weight. The phrase "for administration to an animal" in claim 1 is also viewed as being directed to the intended use of the claimed product. Claims 1 and 2 are anticipated by Knittel *et al.*

27) The rejection of claims 1, 2, 6-10, 12, 32, 37-41, 43, 94, 95, 108, 109, 114 and 115 made in paragraph 32 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 112, first paragraph, as being non-enabled, is maintained for reasons set forth therein and herebelow.

The rejection still applies even with the new limitation: 'sub-type' of *L. intracellularis'* now added to the claims and/or the base claims.

Applicants state that Example 11 teaches a 'formalin-killed *L. intracellularis'* vaccine composition and that Example 12 gives a vaccination protocol of infected controls, vaccinated and uninfected controls. Applicants contend that Example 13 describes pigs which survived the vaccination protocol were 'challenged with the vaccine', and that Example 14 provides for antibodies from vaccinated pigs which recognize various immunodominant proteins. Applicants further submit that Examples 16 and 17 describe the pathology of the three groups and histopathology of intestinal disorders in the infected control group and no gross signs of PPE and conclusive evidence of PIA in the vaccinated group. Applicants assert that they have described and enabled a vaccination and challenge with the 'formalin-killed' *L. intracellularis* vaccine. Applicants state that the specification describes that the specific parts of *L. intracellularis* have been demonstrated to be immunogenic. Applicants state that the proteins that elicit the strongest antibody action have been identified. Applicants contend that lines 1-8 on page 16 describe methods of detecting immunogenic

components and that Examples 4, 5 and 9 describe arriving at the immunogenic components. Applicants assert that specific immunogenic parts of *L. intracellularis* have been enabled and proteins which elicit antibody reactions have been enabled in the present disclosure.

Applicants' arguments have been carefully considered, but are non-persuasive. It should be noted that instant claims are not drawn to a vaccine composition comprising a 'formalin-killed' *L. intracellularis* vaccine and a method of vaccinating or treating an animal with such a composition wherein the composition induces a 'protective immune response' against *L. intracellularis*, or a related microorganism such as an isolate or subtype of *L. intracellularis*, or any other species of the genus *Lawsonia*. On the contrary, the claims are drawn to an isolated polypeptide component of *L. intracellularis* and a method of vaccinating or treating an animal with such a composition wherein the composition induces a 'protective immune response' against *L. intracellularis*, or a related microorganism such as an isolate or subtype of *L. intracellularis*, or any other species of the genus *Lawsonia*. A showing of decreasing the shedding of one particular isolate of *L. intracellularis* by administering to one animal species, i.e., pigs, a whole cell formalin-killed *L. intracellularis* does not provide enablement for the instantly claimed isolated component of *L. intracellularis* and a method of using the same as claimed. Furthermore, the term 'immunogenicity' is not synonymous or equivalent to 'protective immune response'. The art recognizes that an isolated immunogenic microbial component does not necessarily inudce a protective immune response. For the reasons delineated in detail in paragraph 32 of the Office Action mailed 05/30/02 (paper no. 22), the rejection stands.

28) The rejection of claims 41, 43 and 109 made in paragraph 33 of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 112, first paragraph, as being non-enabled, is maintained for reasons set forth therein and herebelow.

Applicants contend that one of skill in the art is enabled for a polypeptide that is 40% similar of SEQ ID NO: 2 in the composition of the invention, which is to be used to elicit an immune response in order to deter an intestinal disease condition in an animal. Applicants submit that with the provided claimed polypeptide, the availability of homology analysis by the varied computer programs in the art utilizing extensive databases, such as, BLAST, one of skill in the art would be enabled to identify and utilize a polypeptide according to the claimed invention for its incorporation

into a vaccine composition to be used in a method according the invention. Applicants contend that one of skill in the art would be not have to undergo undue experimentation with regards to utilizing a polypeptide according to SEQ ID NO: 2 since the specification provides the necessary guidance to identify a candidate homologous sequence.

Applicants' arguments have been carefully considered, but are non-persuasive. The art-available computer programs do not provide a polypeptide that is 'at least 40%' similar to SEQ ID NO: 2 which has the ability to 'induce a protective immune response against *L. intracellularis*, an isolate or 'subspecies' of *L. intracellularis*, or other species of the genus *Lawsonia'*, as recited. Although producing a polypeptide with such a sequence homology may be well within the realm of routine experimentation, obtaining such a polypeptide having at least 40% similarity to SEQ ID NO: 2 and necessarily having the required/recited functions requires considerable quantity of complex and time consuming experimentation that is undue. How to make such a polypeptide variant such that it also possesses the required functional properties is not taught so that one skilled in the art can produce a polypeptide variant that has such a broad protective ability not only against *L. intracellularis*, an isolate or 'subspecies' of *L. intracellularis*, or but also against other species of the genus *Lawsonia*, as recited, and has the capacity to serve as a therapeutic or prophylactic vaccine. Furthermore, the Courts have held that it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. See *Genentech Inc. v. Novo Nordisk A/S Ltd., 42 USPQ2d 1001)*. Moreover, the specification must have been enabling at the time the invention was made (see *In re Wright, 27 USPQ2d 1510*). In the instant application, the polypeptide variant in the claimed method is required to induce a broadly protective immune response in a animal against *L. intracellularis*, an isolate or 'subspecies' of *L. intracellularis*, or other species of the genus *Lawsonia*. No subspecies of *L. intracellularis*, or other species of the genus *Lawsonia* are disclosed or described. The specification does not disclose the precise structural composition of a polypeptide variant having at least 40% continuous or discontinuous sequence homology with the polypeptide of SEQ ID NO: 2. It is emphasized that predictability or unpredictability is one of the *Wands* factors for enablement. The term 'vaccine' requires that the recited element in the vaccine is protective against a specific pathogen or a disease, in this case, more than a specific isolate. Absent a concrete showing, there is no guarantee that such

a polypeptide variant with as mush as 60% dissimilarity with SEQ ID NO: 2 would maintain the critically important conformational and/or broadly protective epitopes and would serve as a prophylactic or therapeutic vaccine. The rejection stands.

29) The rejection of claims 1, 32 and 41 made in paragraphs 34(a) and 34(i)of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

Applicants state that claims 1, 32 and 41 as amended, include the limitation 'sub-type' which is a well understood term to one in the art. Applicants contend that one of skill in the art is aware of the natural variants of microorganisms that exist within a genus and species, which acquire such names as 'strains', 'sub-type' and/or 'isolates' within the art. Applicants submit that one of skill in the art would not find the phrase 'other species of the genus *Lawsonia*' unclear, and that it encompasses *non-intracellularis* species of the *Lawsonia* genus that exhibit characteristics similar to that of sp. *intracellularis*.

Applicants' arguments have been carefully considered, but are non-persuasive. While claims 1 and 32, as amended, include the limitation 'sub-type, claim 42 still contains the limitation 'subspecies'. Absent a description and/or exemplification of other *non-intracellularis* species of the genus *Lawsonia,* a subtype, or a subspecies of *L. intracellularis,* and absent a description of their precise 'characteristics', one of skill in the art cannot understand the metes and bounds of the claims. One cannot envisage how an 'immunogenic component of *L. intracellularis'* differs from the immunogenic component of an 'isolate of *L. intracellularis*', a 'sub-type' or 'subspecies' of *L. intracellularis*. In order for one of skill in the art to induce a 'protective immune response' against a microorganism that is 'related' to *L. intracellularis* or other *non-intracellularis* species the genus *Lawsonia,* one needs to know what microorganism qualifies as such a 'related' microorganism. It is not clear what characteristics should be similar: genetic, antigenic, physicochemical, cultural, or immunogenic characteristics, or some or all of these characteristics. What degree of similarity or relatedness should be met by a microorganism or a species of *Lawsonia* in order to be encompassed in the scope of the above-cited limitations is not understood.

30) The rejection of claims 2, 6-9, 37-40, 43, 109, 114 and 115 made in paragraph 34(j) of the Office Action mailed 05/30/02 (paper no. 22) under 35 U.S.C. § 112, second paragraph, as being

indefinite because of their dependency from the rejected base claim, is maintained for reasons set forth therein.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments.

Rejection(s) under 35 U.S.C. 112, Second Paragraph

31) Claims 1, 2, 6-9, 32, 37-40, 114 and 115 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) The independent claim 94 includes the new limitation "said related microorganism ....." (see last three lines). It is unclear where does the antecedence for "said" comes from.

(b) Claims 1, 6-8, 32, 94 and 95 are vague and indefinite in the recitation: "sub-type of *L. intracellularis*", because it is unclear what is encompassed in this phrase. It is not clear what characteristics or properties an *L. intracellularis* should have in order to qualify as a "sub-type of *L. intracellularis*". How does a 'sub-type' differ from an 'isolate' of *L. intracellularis*?

(c) Claim 9 is vague in the recitation 'wherein said protein is ..... glucarate transporter' because the origin of this protein is unclear. Are all these recited proteins the proteins of *L. intracellularis*, or non-*L. intracellularis* proteins, or are they host animal proteins?

(d) Claim 115, which depends from the amended claim 8, is confusing and/or lacks antecedent basis for the recitation: "said peptide". Claim 43 depends from claim 8, which recites "the protein", but not a peptide. Clarification/correction is requested.

(e) Claim 9 is indefinite and confusing for being in an improper Markush format in the recitation: "further comprising a compound selected from the group consisting of a protein, wherein said protein is ..... and ...". The further comprised 'compound' can be one of the various proteins, but cannot be all. It is suggested that Applicants replace the recitation with: --further comprising a protein selected from the group consisting of ..... and ...--.

(f) Claim 40 is indefinite and confusing for being in an improper Markush format in the recitation: "component selected from the group consisting of a protein, wherein said protein is ..... and ...". The 'immunogenic component' can be one of the various proteins, but cannot be all. It is

suggested that Applicants replace the recitation with: --the immunogenic component is a protein selected from the group consisting of ..... and ...--.

(g) Claims 2, 6-9, 37-40, 114 and 115, which depend from one of the base claims identified above, are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, because of the vagueness or indefiniteness, identified above in the base claim(s).

Rejection(s) under 35 U.S.C. 102

32) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

33) Claims 1 and 2 are rejected under 35 U.S.C. § 102(a) as being anticipated by McOrist *et al.* (*Int. J. Syst. Bacteriol.* 45: 820-825, October 1995) (McOrist *et al.*, 1995).

The term "vaccine" in the instant claims is viewed as the intended use of the claimed component and therefore is not given any patentable weight. The phrase "for administration to an animal" in claim 1 is also viewed as being directed to the intended use of the claimed product.

McOrist *et al.* (1995) taught an isolated and purified *Lawsonia intracellularis* (*IS intracellularis*)-specific DNA. McOrist *et al.* also taught several sarkosyl soluble proteins isolated therefrom following the sonication of whole cells in a buffered saline (see 'Materials and Methods'; Figure 4 legend; paragraph bridging left and right columns on page 823; and Figure 2). That McOrist's (1995) purified DNA or isolated protein macromolecules are intrinsically immunogenic is inherent from the teachings of McOrist *et al.* absent evidence to the contrary.

Claims 1 and 2 are anticipated by McOrist *et al.* (1995).

34) Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by McOrist *et al.* (*Infect. Immun.* 57: 957-962, 1989) (McOrist *et al.*, 1989).

It is noted that the specification at lines 12-14 on page 2 describes that the *Campylobacter*-like organism is the causative agent of Porcine Proliferative Enteropathies (PPE) and refers to it as "*Lawsonia intracellularis*". The term "vaccine" in the instant claims is viewed as the intended use of the claimed component and therefore is not given any patentable weight. The phrase "for administration to an animal" in claim 1 is also viewed as being directed to the intended use of the

claimed product.

McOrist *et al.* (1989) taught outer membrane preparations of an intracellular *Campylobacter*-like oragnism associated with PPE and a sonicated preparation of the *Campylobacter*-like oragnism (see abstract and Figures 1-3). The protein profile showed two major proteins of 55,000 and 70,000 molecular weight and several minor proteins of 25,000 to 27,000 molecular weight ('Results'), some of which were recognized by monoclonal antibodies specific to the *Campylobacter*-like oragnism obtained from proliferative enteritis lesions (see page 961). That McOrist's (1995) sonicated preparation contains isolated protein, carbohydrate, lipid or nucleic acid components or macromolecules that are intrnsically immunogenic is inherent from the teachings of McOrist *et al.* (1989) absent evidence to the contrary.

Claims 1 and 2 are anticipated by McOrist *et al.* (1989).

Remarks

35) Claims 1, 2, 6-10, 12, 32, 37-41, 43, 94, 95, 108, 109, 114 and 115 stand rejected.

To be consistent with the claim language used in claims 8, 9 and 12, and for proper antecedence, it is suggested that Applicants replace the recitation "A vaccine composition according to Claim 6" in line 1 of claim 7 with the recitation --The vaccine composition according to claim 6--. Analogous suggestion applies to claim 37.

36) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

37) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The

transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

38) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER